NATIONAL INSTITUTE OF MENTAL HEALTH, NIH
REQUEST FOR PROPOSAL - SOLICITATION COVER PAGE

REQUEST FOR PROPOSAL NO:	NIMH-00-AI-0005
TITLE:	*LONG TERM EFFECTS OF POTENT ANTIRETROVIRAL THERAPY ON HIV-INDUCED NERVOUS SYSTEM DISEASE*
OMB No.: 0990-0115	**PURCHASE AUTHORITY:** Public Law 92-218 as amended; Note: The issuance of this solicitation does not commit the Government to make an award, or to pay any costs for the preparation and submission of a proposal.
ISSUED BY: Bruce E. Anderson Contracting Officer Contracts Management Branch National Institute of Mental Health, NIH Neuroscience Center Building 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD 20892-9603 E-mail: ba9i@nih.gov Phone (301) 443-2696 or 2234 Fax at (301) 443-0501 Collect calls will not be accepted.	**ISSUE DATE: December 7, 2000** **DUE DATE: April 10, 2001** Note: The official Point of Receipt for the purposes of determining timely delivery is the Contract Management Branch, NIMH. If the Contracting Officer or Designee does not receive your proposal at the place and time specified, then it will be considered late and handled in accordance with PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this solicitation.
NO. OF AWARDS: **PERIOD OF PERFORMANCE:**	One (1) 5 years, beginning on or about **September 30, 2001**
SMALL BUSINESS/ 8(a) SET-ASIDE:	No, NAICS Code 541710 Size Standard: 500 employees
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Attachment 4)
TECHNICAL PROPOSAL PAGE LIMITS: **AWARD WITHOUT DISCUSSIONS:**	No The Government reserves the right to make awards without discussions
POINT OF CONTACT:	Bruce E. Anderson; voice (301) 443-2334; fax (301) 443-0501; E-mail ba9i@nih.gov *No collect Calls will be accepted.*

NOTE: OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIMH WEBSITE AT http://www.nimh.nih.gov/grants/indexcon.cfm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

December 7, 2000

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-00-AI-0005 entitled "Long Term Effects Of Potent Antiretroviral Therapy On HIV-Induced Nervous System Disease." Proposals are being solicited under Full and Open Competitive procedures.

It is expected that one (1) cost-reimbursement, completion contract will be awarded to initiate and conduct this study on or before September 30, 2001, with a base period of five (5) years, and an option period of three (3) additional years.

FOR PROPOSAL PURPOSES, THE OFFEROR MUST PROVIDE A TECHNICAL AND BUSINESS PROPOSAL (BUDGET) FOR THE BASE PERIOD AND THE OPTION PERIOD (TOTAL 8 YEARS).

Special attention should be directed to the technical proposal instructions and business proposal instructions contained in **Attachment 4.**

The documents included with this electronic RFP package are as follows:

I. Streamlined RFP:

- A. Statement of Work (SOW) **(Attachment 1)**
- B. Evaluation Factors for Award **(Attachment 2)**
- C. Deliverables and Reporting Requirements **(Attachment 3)**

II. Standard RFP Instructions and Provisions **(Attachment 4)**
III. Applicable RFP References/Forms/We blinks **(Attachment 5)**

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

An official authorized to contractually bind your organization must sign your proposal. One (1) original and ten (10) copies of your technical proposal, and one (1) original and five (5) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN **4:30 p.m.**, **local prevailing time, on Tuesday, April 10, 2001**, at the following address:

If using overnight delivery service	If using U.S. Postal Service
Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Rockville, MD **20852**-9603	Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD **20892**-9603

Your proposal should consist of:

1. Technical Proposal – see detailed instructions in **Attachment 4**, and requirements in Statement of Work; also include these forms linked in **Attachment 5**: Technical Proposal Cover Sheet, Technical Proposal Cost Summary, Summary of Current and Proposed Activities, Protection of Human Subjects Assurance Identification/Certification/Declaration, Optional Form 310.

   Also required with the technical proposal is a brief description of the educational training taken (or scheduled to be taken) in the protection of human research participants; see page 37, item (11) **Required Education in the Protection of Human Research Participants,** which explains these new regulations.

2. Business Proposal – see detailed instructions in **Attachment 4**; the business proposal can be submitted in the offeror's own format, but it must show detailed costs by cost category, by year, with an accompanying narrative explanation and justification; it is also very helpful to include a diskette with the costs in spreadsheet format (Microsoft Excel); also include these linked forms in **Attachment 5**: NIH-2043, Proposal Summary and Data Record; Disclosure of Lobbying Activities, OMB SF-LLL (one copy), Representations and Certifications (one copy).

Your attention is further directed to the "Proposal Intent Response Sheet" contained in **Attachment 5**. Please complete this form and return it to this office or notify me at the following Internet address: ba9i@nih.gov on or before March 7, 2001. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABLE ON THE INTERNET (NIMH HOME PAGE) AT: http://www.nimh.nih.gov/grants/indexcon.htm.

Questions concerning any areas of uncertainty, which in your opinion require clarification or correction, must be furnished in writing (Fax or email is acceptable) to Bruce E. Anderson, and marked "Offeror's Questions, RFP No. NIMH-00-AI-0005 ".

Sincerely,

/s/

Bruce E. Anderson
Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Attachments: 1-5

ATTACHMENT 1 **[Back to TOC]**
STATEMENT OF WORK
RFP No. NIMH-00-AI-0005

TITLE: LONG TERM EFFECTS OF POTENT ANTIRETROVIRAL THERAPY ON HIV-INDUCED NERVOUS SYSTEM DISEASE

I. Background, Contract Objectives, and Approach

A. Background

HIV enters the nervous system soon after infection, eventually resulting in a range of cognitive, motor, and behavioral symptoms known as HIV-associated dementia (HAD). The more severe form of HAD is referred to as "HIV-1 associated dementia complex" and the mild form is referred to as "HIV- associated minor cognitive /motor disorder." With HAD, unlike cortical dementias, memory impairments occur along with or following other symptoms like inattention, apathy and psychomotor slowing. Motor symptoms are manifested by lack of coordination. Some patients experience neuropsychological (NP) impairments characterized by subtle cognitive and motor changes. Milder and severe manifestations can interfere with patient employment and productivity, independence, and adherence to medication regimens. Another neurologic manifestation is sensory neuropathy, which is associated with persistent pain and paresthesias.

The advent of potent antiretroviral therapy (formerly called HAART, or highly active antiretroviral therapy, herein referred to as ART) has provided significant benefits for HIV infected individuals. Potent ART combines medications from three distinct classes: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PI). In 50-80% of newly treated patients, long-term suppression of viral replication (below levels of detection) is achieved with increases in CD4+ cells. Patients survive longer and have less morbidity. The incidence and prevalence of HIV-induced nervous system manifestations in the era of potent combination ART is not well characterized. Before the introduction of this combination therapy, dementia occurred in about 7-15 percent of patients with AIDS and milder impairments occurred in about 35-50 percent of those with HIV/AIDS. There is some indication that the incidence of central nervous system (CNS) manifestations appears to be declining with the advent of new therapies, but the prevalence may be increasing as patients live longer. However, since the advent of ART there have not been broad, population-based studies of the epidemiology of nervous system manifestations with HIV infection. Nor is there a full understanding of the clinical neurologic disease course because of the lack of longitudinal studies. Furthermore, sensory neuropathy appears to be exacerbated by ART in some individuals.

Evidence for reduction of NP impairment with potent ART is increasing, but many questions remain. ART has been shown to alleviate NP impairments in many individuals, but large studies with broad generalizability are needed to assess whether potent ART has long-term benefits for the full array of HIV-related nervous system impairments.

Although potent ART has beneficial effects for HAD, many of the drugs in this combination therapy show limited penetration of the blood brain barrier. It is unclear if improvements in symptoms observed after drug treatment are due to reduction in CNS viral load or due to viral load reductions in peripheral compartments. Reducing viral load in the periphery may reduce viral trafficking to the CNS. However if the therapeutic agents cannot access CNS viral reservoirs, drug-resistant viral

mutations may occur. The specter of drug-resistant viral strains presents daunting implications for controlling HIV in the CNS and the periphery.

Although ART has had tremendous beneficial effects for many HIV-infected individuals, a number of drawbacks remain. It is not effective for about 20-50% of patients. In addition, these drugs may produce gastrointestinal side effects (nausea and diarrhea), as well as headache and fatigue. Potent antiretroviral therapy is also associated with a body fat redistribution syndrome affecting 30-80% of patients, and may be accompanied by metabolic abnormalities, including insulin resistance, hyperglycemia and hypertriglyceridemia. Therefore, many patients undergo interruptions of their treatment protocols that frequently result in rebound of viral load. How these metabolic complications and treatment interruptions impact on the neurological and neuropsychological status is not known.

B. Objectives, Methods and Approach

The general objective of this contract is to assess the long-term effects of potent ART on HIV-induced disease of the nervous system, focusing on the complete range of neurologic, neuropsychological, and neurobehavioral outcomes of ART therapy. The data collected from these studies will provide a resource for assessment of the impact of CNS infections on overall HIV-1 disease progression. This data resource is particularly significant, given the current intense interest in latent CNS reservoirs and the potential for reseeding of peripheral compartments by drug resistant strains of HIV-1.

The Contractor shall initiate, manage and coordinate a cross sectional and longitudinal multi-site study of five (5) years duration with adequate statistical power to address the above objective, in accordance with an approved protocol. The Contractor shall provide a paradigm for obtaining patient sampling size estimates in order to ensure that reliable conclusions with acceptable statistical power can be drawn from the data. The Government estimates that 4-6 sites will be utilized in this study, to assess 400-500 subjects per year, and that 10-20% of these subjects will be followed for a longer period of time. Sites shall be selected through a competition process, after award, with the concurrence of the NIMH.

As detailed in Services to be Performed, Section III, below, the Contractor will be responsible for central coordination including recruiting study sites, protocol development and finalizing the study design, preparing informed consent documents, providing data forms, training, centralized communication, data entry and management, quality control procedures, site monitoring, statistical analysis, report writing and other related activities. Procedures shall be developed for the collection, storage, retrieval and final disposition of patient samples. For subjects that are going to be followed, the Contractor will need to retain, aliquot and store blood and plasma samples. The Contractor may propose a centralized laboratory site to receive, process, and store study samples.

Specific Study Objectives and Protocol Requirements

Note: The Contractor shall address objectives 1-7 below in the proposed protocol:

1. Assessment of the incidence and prevalence of HIV-1 associated dementia, minor cognitive/motor disorder, and neuropsychological impairments, including depression and anxiety, in HIV-infected individuals at all stages of infection and ART treatment history. Prevalence of neurologic dysfunction will be determined in an epidemiological study as a function of their current viral load and CD4 count, known duration of infection, CSF viral

load status, and CSF immune markers. Incidence of new or recurrent neurologic diagnosis will be determined in a smaller subset of patients that will be followed longitudinally for changes in response to treatment protocols as measured by viral load and CD4 count, known duration of infection, CSF viral load status, and CSF immune markers.

In order to achieve this objective, the Contractor shall develop a protocol for utilization of a comprehensive battery of tests to assess neuropsychological status, covering measures of attention, memory, constructional abilities, psychomotor speed, and impact of infection on daily living.

2. Evaluation of the viral genotype in CSF, plasma, and other body compartments such as bone marrow, lymph nodes, etc. as well as the brain (if autopsy tissue is available) following potent ART in a subset of patients. The criteria for selection of patients for genetic analysis will be outlined in the final study protocol.

3. Assessment of neuroimaging correlates in a subset of subjects with HAD, minor cognitive/motor disorders, and neuropsychological impairments, to track changes in unique signatures associated with specific HIV-induced neuropsychiatric or cognitive dysfunction in the context of potent ART. The criteria for selection of patients for neuroimaging studies will be outlined in the final study protocol.

4. Assessment of CNS and peripheral nervous system (PNS)-related side effects resulting from potent ART such as abnormal lipid metabolism, mitochondrial dysfunction and peripheral neuropathy.

5. Assessment of drug interactions between ART and psychotropic or other medications. This assessment shall include the impact of ART on concentration and effectiveness of other drugs, as well as the converse.

6. Also as part of this contract, the Contractor shall actively encourage the submission of investigator-initiated ancillary studies. Ideally each clinical site will have existing strong collaborative interactions between the clinical investigators and basic science investigators to facilitate studies on the molecular and cellular mechanisms underlying neurologic complications of HIV infection. Ancillary studies are encouraged, and any investigator can propose ancillary studies if they enhance the value of the overall initiative. Funding for ancillary studies will not be provided in this contract and must be submitted as separate research project grants (R01). The NIMH will not consider ancillary studies for review without a letter from the Coordinating Center stating that the study meets the following objectives: 1) an ancillary study must be judged scientifically meritorious and operationally feasible; and 2) an ancillary study will not be considered for inclusion if it is judged to have the potential for interfering with the completion of the main objectives of this contract, if it adversely affects subject availability or cooperation, if it diverts resources from this contract, or if it negatively affects the public image of this contract.

7. This contract will provide ready access to the data and collected biological samples in order to encourage further research in NeuroAIDS and its impact on HIV disease progression.

Subject Inclusion and Exclusion Factors

The Contractor and sites shall gather current and on-going data on HIV positive individuals who:

1) are currently undergoing antiretroviral treatment for HIV infection;
2) are about to start antiretroviral treatment (pretreatment);
3) have undergone ART treatment and stopped (treatment interruption); and/or,
4) are taking psychotropic or other medications in combination with ART.

The Contractor can recruit and follow new subjects and/or gather additional data on subjects already enrolled in another clinical trial. The majority of the patients in this study will be evaluated once, however, as stated in the above specific objectives, a subset of patients shall be followed over a longer period of time. The final study protocol will outline the criteria for follow-up of this group of subjects. The estimated 400-500 subjects per year thus include both subjects evaluated once and those being followed.

The Contractor and sites shall gather data on individuals from a broad variety of health care settings, geographically dispersed, with broad subject inclusion criteria that closely resembles the type of HIV patients typically seen in health care settings. **Subjects shall include, as much as feasibly possible, women, minority, and children populations, in accordance with NIH regulations.**

There shall be no new treatment protocol initiated on subjects included in this contract (i.e., no new drugs shall be administered, and there is no control group for evaluation). Rather, this contract will evaluate individuals at various stages of their individualized treatment plan. There shall also be no HIV screening conducted. Subjects shall have already been evaluated and have tested positive for HIV infection by a clinic/physician.

In addition to having access to a sufficient number of potential sites and subjects, the Contractor and sites shall have access to appropriate laboratory facilities, computer equipment, and neuroimaging equipment. The Contractor and the sites shall also have access to a standing Institutional Review Board (IRB) with multiple project assurance from the NIH Office of Human Research Protections (OHRP), or commitment to acquire a single project assurance from OHRP.

II. Other Information

A. Organizational Components

This contract will involve a multimember effort and a collaborative relationship between the principal investigator (PI), clinical site investigators, the GPO and other NIH staff.

The main organizational components of the study will be: 1) the Coordinating Center, and any appropriate subcontractors; 2) the Research Sites; 3) a Steering Committee comprised of the PI's from each of the study sites and the Coordinating Center, the NIMH Government Project Officer (GPO) and other selected NIH staff; and, 4) a Publications Committee that will include representatives of the Coordinating Center, study sites, and GPO, which will plan and coordinate publication activities from the study.

The GPO and the NIH scientists will participate in scientific oversight of the study along with the External Advisory Committee (EAC), a group of independent scientific reviewers to be

established by the funding Institutes to provide methodological consultation. The Principal Investigator of the Coordinating Center shall direct the scientific and day-to-day operational aspects of the study.

B. Phases

The contract shall have two major phases, discussed in more detail below in Section III.

- Phase 1 (months 1-12) – involves finalization of the study protocol, selection and training of clinical sites, study preparation, preparation for data collection and management.

- Phase 2 (month 13 on) – involves protocol implementation (enrollment, study coordination and administration)

C. Option Period

The need may exist to extend the contract beyond the initial period of 5 years. The Government anticipates that extra time may be needed to take advantage of new information or new treatments that become available after the start of the contract. In addition, a subset of individuals with HIV disease may be identified during the contract period for which longer follow-up will substantially increase our understanding of HIV/nervous system disease and its response to current therapeutic interventions. Thus, there will be one (1) option to extend the term of the contract for an additional three years, to follow this subset of patients.

It is estimated that this study will continue to evaluate and assess 200-300 patients/year at the estimated 4-6 sites, in accordance with an approved protocol to be finalized during the course of the option period.

III. Services to be performed

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities, needed to function as the Coordinating Center for this contract entitled "Long Term Effects of Potent Antiretroviral Therapy on HIV-induced Disease of the Nervous System". All work under this contract will be conducted under the general guidance of the Government Project Officer (GPO).

A. Phase 1

1. Finalization of the Study Protocol

After award of the contract, the Contractor shall promptly begin the process of finalizing the draft protocol. It is estimated that this process will be completed within 12 months.

An estimated milestone schedule for completion of the final protocol is as follows:

- Within 3 months - convene a workshop(s), to reach a consensus on the parameters of the protocol
- Within 5 months – submit draft protocol to Steering Committee for review
- Within 6 months – submit a final draft to the GPO
- Within 12 months – Final approval of the protocol by the GPO and the NIMH

The final protocol shall include, at a minimum, the following aspects:

a. A review of study objectives and endpoints
b. Study design
c. Consent documents
d. Patient selection criteria with rationale for exclusions
e. Sample size and power estimates
f. Laboratory procedures
g. Identifying and obtaining neurological and neuropsychological batteries
h. Handling/storage and disposition of human specimens
i. Plans for coordination of imaging studies
j. Study and laboratory monitoring procedures
k. Plans for preventing, identifying and handling protocol violations
l. Plans for study staff training
m. Plans for monitoring and coordinating study sites
n. Plans for cross-site quality control and standardization
o. Data collection and monitoring
p. Human subjects consideration
q. Periodic data review
r. Plans for final data analysis
s. Rules for possible protocol adjustments

The GPO shall review the final draft protocol within two weeks of submission by the PI, and shall recommend any changes that should be made (if any). The final protocol will require approval by the GPO.

2. Selection of Clinical Sites and Subcontract Terms and Conditions

a. General

After award of the contract, the Contractor shall promptly begin the process of site selections. It is estimated that within12 months after award, the Contractor will negotiate and award subcontracts (for approximately 4-6 sites) with the capability of assessing 400-500 patients per year, and adequately train site personnel. The Contractor shall select sites that have sufficient number of patients/subjects to ensure prompt recruitment.

The Contractor shall have a system in place for selecting, awarding, training and managing study site subcontracts that conforms to the requirements of the contract; the Contractor shall continue to maintain such a system throughout the contract term. The Contractor will not enter into any subcontract that has not received the scientific and

technical review of the GPO and has been approved in writing by the Contracting Officer.

The Coordinating Center will obtain a proposal from each prospective site, which includes a plan for implementation of the protocol, a fixed cost per subject, and the adequate documentation showing that the criteria listed below can be accommodated. Sites should also document collaborative efforts bridging clinical and basic research.

b. Evaluation of Prospective Sites

The Coordinating Center shall propose a review process by which the prospective sites will be ranked according to the following criteria:

(1) Access to a sufficient number and type of potential study participants to ensure: the prompt enrollment of the study subjects; the patient population will be geographically dispersed; the patient population will be inclusive of women and minorities to be representative of the ethnic diversity of patients; the subjects will be treated in a variety of treatment settings, including university settings, private practice, and/or managed care, capable of providing state of the art HIV medical care; and the subject population will include subjects of both genders (ages 18 and over) meeting all other study entry criteria;

(2) Investigators experienced in conducting studies involving HIV and CNS disease;

(3) Availability of well-qualified and experienced professional and technical staff to provide scientific and administrative expertise to the study site, including quality control expertise and appropriate clinical expertise; experience in similar complex multi-site trials with patient recruitment and follow-up;

(4) Adequate facilities and equipment to conduct the study, such as computer and electronic communication capabilities;

(5) Data management capabilities including data collection, data entry, edit transfer and quality control;

(6) Access to a standing Institutional Review Board (IRB) with multiple project assurance from the Office for Human Research Protections (OHRP), or commitment to acquire a single project assurance from OHRP;

(7) Agreement to comply with all the required Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition Regulation (HHSAR) clauses that apply;

(8) Acceptance of the proposed fixed site costs falling within the amounts included in the contract proposal and negotiated in the Coordinating Center Contract;

(9) Ability to track and retain subjects for 4 to 7 years;

The Coordinating Center will evaluate and rank the site proposals, and forward recommendations for subcontracts to the GPO. The Contracting Officer shall approve/disapprove sites within two weeks from receipt of this submission. The Contractor

shall promptly execute subcontracts and train site personnel, after receiving the Contracting Officer's concurrence.

c. Terms and Conditions for Study Site Subcontracts

(1) At the time of subcontract award(s), the site PI's shall have an established source of research subjects appropriate for the protocol design.

(2) All research activities conducted at each study site will follow the state-of-the-art of good clinical practice criteria, in order to generate data that can be published in peer-reviewed leading scientific journals.

(3) All institutional, NIMH, and federal regulations concerning informed consent must be fulfilled. Protocols and patient consent forms will be approved by the appropriate IRB.

(4) All materials/data collected by the PI from the specific study funded under this contract will be the property of NIMH and will be made available to the NIMH both electronically (in PC format) and in hard copy using standard procedures that safeguard the confidentiality of the research records. It is anticipated that the GPO and other Government officials involved in the activities conducted under this contract will publish data jointly with the contractor and other study site staff.

(5) NIMH or it designees will have the right to audit patient records and research data at any time during the study.

(6) The Contractor will be responsible for all aspects of the performance of this contract including the performance of any subcontracts. Any subcontract requires prior review and approval of the Contracting Officer (CO) before award.

(7) The GPO and the Prime Contractor will monitor all work under this contract.

(8) The PIs of the clinical sites will be considered as Key Personnel and may not be replaced without prior approval of the CO, the GPO, and the Prime Contractor.

(9) The sites shall have proper facilities for collecting, processing, and storing human tissue samples, and in general all necessary equipment and facilities for performance.

3. Study Preparation

Study preparation activities involve the process of finalizing the study protocol (see item 1. above), selecting the sites and training the sites (see item 2. above), and design of the data collection and management system (see 4. below). It is estimated that all study preparation activities will be completed in year 1.

The following types of tasks, some of which are to be included in the final protocol, shall be completed before initiation of the study:

[Note: the following list may not be all inclusive of preparatory activities needed]

a. Prepare manuals of study procedures for the CC and sites; arrange and coordinate training of the site staff, in order to ensure reproducibility of evaluation and assessment procedures;

b. Develop the text of the study consent and assent forms for use by the study sites, provide the sites with such documents, and ensure that, after appropriate modifications to meet local standards, these forms are submitted and approved by the IRB at each site;

c. Develop a system of subject selection that ensures a appropriate distribution of patient characteristics;

d. Develop a plan for overall quality control, for monitoring patient recruitment, and for early identification of sites with recruitment problems and for addressing recruitment difficulties;

e. Develop and produce standardized research forms for collecting all the data needed on the study subjects;

f. Pilot test all forms and procedures before their finalization and distribution to sites;

g. Develop plans for handling data (see 4. below) and human tissue samples.

h. Develop plans to obtain IRB approval of the final protocol.

i. Submit to the GPO all materials necessary to obtain approval of a clinical exemption from the NIH Clinical Exemption Review Committee before the start of patient enrollment into the protocol and all materials necessary to obtain approval of the Office of Management and Budget (OMB) if required;

j. Develop an evaluation plan for monitoring the sites progress, including plans for dropping a site and adding new sites should recruitment goals not be met.

k. Develop plans for periodic conference calls with sites;

l. Develop plans for publicizing information about the study including developing a web site.

4. Data Collection and Management System

The Coordinating Center shall prepare/design a computer-based data collection system and data management system. It is estimated that this system will be designed and tested by the end of year 1.

The data entry may be centralized at the Coordinating Center or done electronically at each site. In the latter case, the Coordinating Center may choose to provide a standardized data management system to each study site, or work with existing compatible management systems at each site.

At a minimum, the Coordinating Center system will provide the following:

a. A standardized method of data entry, data verification process, and point-of-entry data checking system;

b. A method of data transfer from the study sites to the Coordinating Center, with ability to receive, process, edit, correct, update, store, track, retrieve, and analyze all study data; such system will be tested prior to patient recruitment to ensure reliable transfer of data from each of the study sites to the Coordinating Center and from the Coordinating Center to NIMH;

c. A method to ensure the security and confidentiality of all the clinical records. In particular the Coordinating Center will be prohibited from collecting or maintaining information about any patient enrolled in the research study, which would allow the individual to be personally, and directly identified in the study database developed/maintained at the Coordinating Center;

d. Ready transfer of data and data documentation to NIMH at any point in the study. Equipment at the contractor's site shall be compatible with NIMH equipment for electronic data transfer and mail communications (e.g. the Internet). The Contractor may be required to electronically transmit the database to NIMH upon request;

e. Sufficient flexibility and accessibility to answer inquiries in a timely manner, typically in no more than one day. The database will be structured to allow information to be retrieved in a flexible and convenient manner for statistical analysis and preparation of a variety of reports;

f. The capability for monitoring the study site data collection, forms tracking, and transfer of data from the sites to the Coordinating Center. The Coordinating Center will train staff at the study sites in proper procedures and standards to ensure prompt accumulation, completeness, entry and editing of study data. If data are entered at the sites, procedures for entering and verifying entered data will be specified:

g. The capability for monitoring the accuracy and completeness of the centralized database as well as for resolving problems identified in the monitoring process;

h. The capability to verify, process, monitor, correct, update, file, store and maintain an inventory of data securely using the computerized data management system developed. Data received from the clinical sites will be reviewed within one week from the receipt for completeness, accuracy, consistency, out-of-range values and overall quality. Sites will be informed promptly, and in any case within two weeks from the data receipt by the Coordinating Center, of any missing, incomplete, or erroneous data.

i. Appropriate methods of analysis and presentation of study data. The Contractor shall use a GPO approved statistical package with capability of univariate and multivariate analysis.

At the completion of the contract, the Coordinating Center shall provide the GPO with three copies of the final, cleaned, edited, and documented data set containing all study data in an electronic format specified by the GPO, together with full supporting documentation (i.e., programming information, source code, code books, etc), and final statistical reports of the study outcomes.

B. Phase 2

1. Protocol Implementation

It is estimated that enrollment into the study protocol will start approximately 12 months after contract award. During the enrollment period, the Contractor will perform all the activities necessary for proper conduct of the study, including but not limited to, the following:

a. Monitor sites for rate of recruitment, protocol adherence, data collection, data entry and quality assurance at each site;

b. Ensure accurate data transfer from the sites to the Coordinating Center;

c. Assess the quality of the data received from the sites and through periodic site visits check the database with the source of documentation;

d. Prepare and send monthly reports on the state of the study to the GPO. After starting recruitment, the monthly reports will include, at a minimum, the following information:

   i. number of patients enrolled by each site as well as cumulative total;
   ii. demographics of patients enrolled,
   iii. number of patients screened but not enrolled with reasons for non enrollment;
   iv. number of patients who dropped out of the protocol and reasons;
   v. number of patients who have completed the assessment protocol;
   vi. anticipated/projected patient enrollment and completion schedules

e. Prepare and distribute other reports to the GPO and Contracting Officer, as requested.

2. Meetings/Communications

At a minimum, the following tasks shall be performed in order to effectively coordinate and manage the study:

a. Schedule and coordinate periodic telephone conference calls with the GPO, other NIMH staff, advisors, and other staff involved in the study, in order to discuss the progress of the study and other project related activities. The frequency of these calls will depend upon the phase of the study, complexity of issues, actual progress and problems encountered. The Contractor shall prepare minutes of these calls and send them to the GPO and other relevant parties within 4 working days after each call.

b. Schedule, coordinate, arrange, participate in, and provide any information necessary for the Steering Committee meetings. These meetings will have a frequency ranging from two to three times per year, as required by the phases and progress of the study. It is anticipated that in year 1 a two-day meeting will be convened before starting recruitment, in order to review the protocol and plan training. The Contractor shall prepare minutes of these meetings and distribute to the GPO and other relevant parties within 7 working days after each meeting.

c. Attend and participate in the meetings of the External Advisory Committee. It is estimated that advisors will meet once or twice per year, based on the phase and progress of the study.

d. Schedule, arrange and coordinate meetings with the study site staff with the purpose of training staff in all the relevant activities of the study. It is anticipated that one (1) training meeting will be required within the first 12 months after contract award.

e. Arrange for regular site visits, at least once a year, at each participating site, with the purpose of monitoring adherence to protocol and ensure consistency across sites and quality control the data collected and entered in the database. A schedule for these visits will be established annually, and provided to the GPO who may choose to attend any or all of these visits. The Contractor will prepare a written report for the GPO on the results of each visit and will send to the site and the GPO within 15 working days after completion of the visit. Reports will indicate number of clinical files and procedures reviewed, number and types of protocol violations or deviations encountered, and number and types of discrepancies between the database and the source documents. Reports shall include recommendations and plans aimed at correcting any problems encountered at the study sites.

IV. Miscellaneous Provisions

The Contractor must agree to the following terms:

1. All tasks described in this statement of work will be coordinated and implemented by the Contractor in conjunction with and under the guidance of the GPO.

2. The data collected under this contract will belong to the Government. It is understood that the Coordinating Center, working in conjunction with the Steering Committee, the External Advisory Committee, and the GPO, will expeditiously prepare reports on the study results for publication in peer reviewed scientific journals. These publication activities will be coordinated by an ad hoc constituted Publication Committee, which will include Principal Investigators at the Coordinating Center and at the study sites, and the GPO.

3. No data from studies funded under this contract may be released, presented at meetings or published without prior review and approval by the Publications Committee, and without the concurrence of the GPO, until all the primary reports have been published. After all the primary papers have been published, copy of the database will be made available directly to each PI involved in the study and other reports for publications may be produced without the approval of the GPO, but with appropriate acknowledgement of the contract as a source of data.

4. It is anticipated that the GPO and other NIMH staff actively involved in the scientific aspects of the study will publish study data jointly with the Principal Investigator and other contract personnel, and the clinical site PI's.

5. The GPO may require that reports and data be transferred directly from the Contractor or site subcontractors to an independent site for analysis.

6. The Contractor shall establish procedures to safeguard the confidentiality of any proprietary information provided by the GPO at the sites.

7. The GPO reserves the rights to interact directly with the clinical sites and appoint consultants to ensure that contract-related activities meet all the requirements agreed in the contract and are performed in accordance with standards and requirements of NIMH.

V. Reporting Requirements and Deliverables

In addition to any ad hoc reports requested by the GPO, the Contractor shall submit Technical Progress Reports covering the work accomplished during each reporting period (as outlined below)

1. Monthly Study Reports

The Contractor shall submit one copy to the GPO and one copy to the Contracting Officer (CO) of the monthly report within ten days following the end of the month. At a minimum this report will include a description of the study progress, quality of data, problems encountered and their resolution and study site enrollment data such as:

- patients enrolled in the study and their demographic characteristics,
- patients screened but not enrolled and reasons why not enrolled,
- patients that have been assessed, and type of assessment
- anticipated patient enrollment and completion requirement for the remainder of the study.

The report will present overall study information as well as data for each study site. Problems in recruiting and plans for correcting recruiting problems must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution should be included.

2. Annual Report for Gender/Minority Tracking

Annually the Contractor shall submit one copy with a recruiting report detailing the following information: Report date, date enrollment/recruitment was initiated, date enrollment/recruitment was completed, identify whether a minority sub-population has been identified, and a count of patients TARGETED by gender and by ethnic group (American Indian or Alaskan Natives; Asian or Pacific Islanders; Black, Not of Hispanic Origin; White, Not of Hispanic Origin; Other or Unknown). A similar count of patients RECRUITED by gender or ethnic background must be included.

3. Study Final Report

The Contractor shall submit to the GPO two hard copies and one electronic copy (in PC format) of the Final Report on or before the contract completion date. The report will include a summation of the work performed and results obtained. The report will be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved and shall

summarize data analyses performed in text, tabular and graphical form. One copy of this report shall also be provided directly to the CO.

4. Final Data Set(s) and other Materials/Samples

   a. Data: At the completion of the contract, the Coordinating Center shall provide the GPO with three copies of the final, cleaned, edited, and documented data set containing all study data in an electronic format specified by the GPO, together with full supporting documentation (i.e., programming information, source code, code books, etc), and final statistical reports of the study outcomes.

   b. Other Materials: All other materials/ patient samples collected by the PI from the specific study funded under this contract will be the property of NIMH and will be made available to the NIMH upon request. This includes aliquots of plasma and CSF samples, all manuals and others materials developed as a result of this contract.

ATTACHMENT 2 **[Back to TOC]**
EVALUATION CRITERIA FOR AWARD
RFP No. NIMH-00-AI-0005

A. GENERAL-BASIS FOR AWARD

Selection of an offeror for contract award will be based on an evaluation of proposals against three (3) factors. The factors, in order of importance are: technical, cost and small disadvantaged business participation (SDBP). Although technical factors are of paramount consideration in the award of the contract, both SDBP and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The offeror's plan for inclusion of women, members of minority groups, and children in this study will also be evaluated, and must be considered acceptable before an award can be made (see section F., below).

Offers form qualified HUBZone firms and small disadvantaged business concerns may have special evaluation terms (see below). The small disadvantaged business participation (SDBP) factor is explained in E. below.

Offerors are advised that award will be made to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Proposals are intended to be evaluated and award made after discussions with offerors, but an award may be made without discussions with offerors.

B. TECHNICAL EVALUATION CRITERIA AND ASSIGNED WEIGHTS

Proposals submitted in response to this RFP will be judged solely on the written material provided by the offeror. The maximum score for a proposal is **100 Points**.

Proposals will be evaluated based on the following factors, which are **weighted in order of their relative importance (including sub-criteria)**:

1. TECHNICAL APPROACH **40 Points**

The proposal should demonstrate soundness and practicality of the technical approach for executing the entire set of requirements specified in the Statement of Work, with adequate justification and substantiation for the recommended methods; also, demonstration of Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. The evaluation will assess:

a. Scientific value of the proposed study protocol. The Offerors should develop and fully elaborate the key elements of the study design, addressing the study objectives in the Statement of Work. The offeror should present a detailed protocol including, but not limited to, the following aspects:

- Elaboration/discussion of the research objectives and clearly outlining the proposed experimental methodology for accomplishing these objectives;
- Discussion of any previous data and literature;
- Power analysis of the main study;
- Plans for ensuring consistent and replicable administration of the protocol both within and across sites, during the duration of the trial;
- Plans for ensuring consistent and replicable assessment of the clinical variables of interest, both within and across sites during the duration of the trial.
- Plans for collection of data and ensuring quality control of the data collection.
- Data analysis.

b. Quality control procedures to ensure: a reliable well-monitored, efficient, and responsive study with an effective data management system, procedures to handle data from multicenter clinical sites, and for interfacing with NIMH and study sites.

c. Technical approach for providing statistical scientific leadership and advice in planning assigned collaborative research efforts and for conducting and interpreting statistical analysis.

d. Technical approach for recruiting and coordinating sites. Plans for recruiting sites with appropriate infrastructure and experience in conducting clinical studies in HIV induced neurological and neuropsychiatric disease. Approach for coordinating the study to include logistical aspects, training and interactions, including the cultivation of commitment of participating clinical sites, and ensuring they recruit adequate numbers of subjects, and maintaining productive interactions among them.

2. PERSONNEL AND MANAGEMENT PLAN **30 Points**

a. Quality and experience of the Principal Investigator. The Principal Investigator should have substantial expertise in providing scientific oversight of clinical studies/trials, HIV related neurologic and neuropsychiatric disorders, statistical and data management activities of multi-center clinical trials. Evidence that the P.I. is adequately available to this project and is not over committed with regard to other duties.

b. Quality and experience of the other personnel at the Coordinating Center. The team of professional personnel should have documented medical and scientific qualifications required for coordinating HIV clinical studies/trials. Evidence should be provided of active collaboration with a range of HIV treatment providers, including experience recruiting and monitoring clinical sites. Evidence that key staff is adequately available to this project and are not over committed with regard to other duties. The administrative personnel must show budgetary expertise in managing multiple subcontractors with varying payment levels. The computing staff should possess documented expertise in computer methods for data management and statistical analysis of clinical data, electronic connections to remote systems (if proposed) and proficiency with software and operating

system(s) proposed to accomplish the statement of work, including some proficiency with standard commercial software as necessary.

c. Management Plan. The management plan for this study should demonstrate the adequacy of the administrative framework, clear lines of authority and responsibility, and adequacy of the plan to accomplish tasks. Time schedules and cost projections should be realistic and satisfactory for achieving contract objectives while maintaining quality control. The P.I. and the research team should have experience working together as a unit.

3. QUALITY OF POTENTIAL CLINICAL SITES **20 Points**

The quality of the proposed network of clinical sites will be evaluated, including organizational experience conducting similar studies, expertise and experience of the personnel, evidence of adequate patient flow, and ability to recruit patients in a timely manner. Documentation should be provided of each site's field experience working in and recruiting patients within managed care settings, private practices, university clinics and hospital clinics and monitoring compliance with such activities. Evidence should be provided that key personnel at the sites are available to this project and are not over committed with regard to other duties.

4. ORGANIZATIONAL EXPERIENCE AS A COORDINATING CENTER; OTHER FACILITIES AND RESOURCES **10 Points**

a. Organizational Experience. Prior organizational experience in comparable multi-center clinical trials management including documented experience in recruiting clinical sites and ensuring recruitment goals are met, adequate training of staff, collecting data from multiple sites, experience monitoring the quality and timeliness of such data, and a description of anticipated problems in this trial and plans for their resolution.

b. Facilities and Resources. Adequacy and availability of the facilities and resources necessary for conducting this study; availability of computer hardware, software and other equipment, in order to successfully implement the requirements of this contract. Availability of other organizational personnel as resources to provide occasional consultation and assistance. Upper level management's level of support for this study.

TOTAL POINTS **100 POINTS**

C. HUBZONE SMALL BUSINESS CONCERNS

Offers from Qualified HUBZone firms:

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

D. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

Offers from Small Disadvantaged Business firms:

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Attachment 5, RFP References, offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23, which can be found on-line at http://www.arnet.gov/far/

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

E. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR (SUBJECTIVE ASSESSMENT)

Offers from Other than Small or Small Disadvantaged Business firms:

Evaluation of the Offeror's Small Disadvantaged Business Participation Plan will be based on information obtained from the plan provided by the offeror (with their business proposal), the realism of the proposal, other relevant information obtained from named SDB concerns, and any information supplied by the offeror concerning problems encountered n SDB participation.

Evaluation of SDB Participation Plans will be a subjective assessment based on a consideration of all relevant facts and circumstances. The government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor. The assessment of the offeror's SDB Participation Plan will be used as a means of evaluating the relative capability and commitment of the offeror and the other competitors. Thus, an offeror with an exceptional record of participation with SDB concerns may receive a more favorable evaluation than another, whose record is acceptable, even though both may have acceptable technical proposals.

SDB Participation will NOT be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB participation Plan will be influential in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered most advantageous to the Government.

F. HUMAN SUBJECTS – INCLUSION OF WOMEN, MEMBERS OF MINORITY GROUPS, AND CHILDREN

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NCI will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

G. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

ATTACHMENT 3 **[Back to TOC]**
REPORTING REQUIREMENTS AND DELIVERABLES
RFP NO. NIMH-00-AI-0005

In addition to any ad hoc reports requested by the GPO, the Contractor shall submit Technical Progress Reports covering the work accomplished during each reporting period (as outlined below)

1. Monthly Study Reports

The Contractor shall submit one copy to the GPO and one copy to the Contracting Officer (CO) of the monthly report within ten days following the end of the month. At a minimum this report will include a description of the study progress, quality of data, problems encountered and their resolution and study site enrollment data such as:

(a) patients enrolled in the study and their demographic characteristics,
(b) patients screened but not enrolled and reasons why not enrolled,
(c) patients that have been assessed, and type of assessment
(d) anticipated patient enrollment and completion requirement for the remainder of the study.

The report will present overall study information as well as data for each study site. Problems in recruiting and plans for correcting recruiting problems must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution should be included.

2. Annual Report for Gender/Minority Tracking

Annually the Contractor shall submit one copy with a recruiting report detailing the following information: Report date, date enrollment/recruitment was initiated, date enrollment/recruitment was completed, identify whether a minority sub-population has been identified, and a count of patients TARGETED by gender and by ethnic group (American Indian or Alaskan Natives; Asian or Pacific Islanders; Black, Not of Hispanic Origin; White, Not of Hispanic Origin; Other or Unknown). A similar count of patients RECRUITED by gender or ethnic background must be included.

3. Study Final Report

The Contractor shall submit to the GPO two hard copies and one electronic copy (in PC format) of the Final Report on or before the contract completion date. The report will include a summation of the work performed and results obtained. The report will be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved and shall summarize data analyses performed in text, tabular and graphical form. One copy of this report shall also be provided directly to the CO.

4. **Final Data Set(s) and other Materials/Samples**

a. Data: At the completion of the contract, the Coordinating Center shall provide the GPO with three copies of the final, cleaned, edited, and documented data set

containing all study data in an electronic format specified by the GPO, together with full supporting documentation (i.e., programming information, source code, code books, etc), and final statistical reports of the study outcomes.

b. Other Materials: All other materials/ patient samples collected by the PI from the specific study funded under this contract will be the property of NIMH and will be made available to the NIMH upon request. This includes aliquots of plasma and CSF samples, all manuals and others materials developed as a result of this contract.

ATTACHMENT 4 [Back to TOC]
INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS
RFP NO. NIMH-00-AI-0005

1. GENERAL INFORMATION

1. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (February 2000)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*" or "*written*" means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended

to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data*. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall--

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with--the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The

data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). Substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

2. "**JUST IN TIME**"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit **an acceptable** subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in **ATTACHMENT 4**, Section.2.c. (1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. [The information may also include submission and certification of cost or pricing data.]

3. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (see http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees .

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

4. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, which will be incorporated in Section I.3.of any resultant contract, offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

5. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about September 30, 2001 .

It is anticipated that the award from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF 5 years, and that incremental funding will be used [see **ATTACHMENT 4**, Section 2.c. Business Proposal Instruction].

6. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

7. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

8. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

9. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in **ATTACHMENT 2** of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

10. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

11. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Contract Management Branch
National Institute of Mental Health
ORM, Room 6107
6001 EXECUTIVE BLVD (MSC 9603)
BETHESDA, MD 20892-9603

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

12. **LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS**, PHS 352.215-10

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government, and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement (completion) type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the cover letter to this Request for Proposal.
Proposals will be typewritten, paginated, reproduced on
letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to

conduct negotiations. (See **ATTACHMENT 5**, form entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any) and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Confidentiality of Proposals--HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984)**

The proposal submitted in response to this request for proposals may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; **provided**, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act, and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."

NOTE: Offerors are cautioned that proposals submitted with the restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in ATTACHMENT 2 of this RFP.

(8) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(9) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(10) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR, (telephone: 301-496-7041), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(11) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(12) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 at the following web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

A complete copy of the updated Guidelines is available at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm

The revisions relate to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all contractors to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See **ATTACHMENT 2** of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See Attachment 5 - List of Documents, Exhibits and Other Attachments of this RFP) shall be used in proposal preparation.

(13) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would

otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

(14) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety-monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at

http://grants.nih.gov/grants/guide/notice-files/not98-084.html

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(15) **Privacy Act**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(16) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or

otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIMH's policy to conduct discussions with all offerors in the competitive range, NIMH reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(17) **Small Business Subcontracting Plan**

******** ***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in ATTACHMENT 4, Section 1.a. of this RFP. *******

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9. For an example of such a plan, see **ATTACHMENT 5** to this RFP.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not

limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer, which will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan, which is provided, as an attachment to this RFP in Attachment 5.

(18) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified

HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(19) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in ATTACHMENT 2 shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size/NAICS-cover-page.htm

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value-$1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines Contractor team arrangements to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that subcontractors present SDB joint ventures and teaming arrangements at the prime level separately from SDB participation.

(20) **Salary Rate Limitation in Fiscal Year 2000 ****

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The salary rate limitation set by P.L. 106-113 applies only to Fiscal Year 2000 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level II."

***This rate may change periodically. For your information, the rate can be found at: http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm**

Note: FY-2001 Public Law and Salary Rate information will replace this and be inserted into the contract upon passage of DHHS FY-2001 appropriation legislation.

(21) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(22) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(23) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project, as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's

best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement.

Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (ATTACHMENT 2, hereof).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points), which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime

contract. For each subcontract over $500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.806.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at:
http://rcb.nci.nih.gov/forms/cpi.htm

(3) **Qualifications of the Offeror**

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts are defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(4) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

> Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

(5) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) **Proposer's Annual Financial Report**

******** ***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in ATTACHMENT 4., Section 1.a. of this RFP. *******

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(7) **Representations and Certifications**

One copy of the Representations and Certifications found as a link in **ATTACHMENT 5**, shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) **Travel Costs/Travel Policy**

a) **Travel Policy**

******** ***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in ATTACHMENT 4, Section 1.a. of this RFP. *******

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

ATTACHMENT 5 **[Back to TOC]**
APPLICABLE RFP REFERENCES/FORMS/WEB LINKS
RFP NO. NIMH-00-AI-0005

A. Sample Contract Format- General

This website outlines a "typical" format for Sections B-J of a contract document. This schedule is provided for informational purposes only. The contract schedule set forth in the website below contains information pertinent to many types of R&D solicitations done at the NIH. The Schedule is not an exact representation of the proposed contract document. For example, contractual provisions pertinent to an Offeror's organizational structure (e.g., Non-Profit, Commercial) and specific costs requiring Contracting Officer prior approval will be negotiated and included in the contract.

http://www4.od.nih.gov/ocm/contracts/rfps/SAMPKT.HTM#F

B. General Clauses and Provisions

The following general clauses and provisions are applicable to this specific RFP and are located on-line at the URL http://rcb.nci.nih.gov/clauses/clauses.html

Any resultant contract will include clauses applicable to your particular type of institution (e.g. educational, for-profit etc.). These clauses are provided for informational purposes only, but may be discussed during negotiations.

C. Forms, Formats And Attachments

The following items are applicable to this specific RFP and are located on-line at URL http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm under the heading Forms, Formats and Attachments.

1. SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

    a. Technical Proposal Cover Sheet
    b. Summary of Current and Proposed Activities
    c. Technical Proposal Cost Summary
    d. Protection of Human Subjects Assurance, Identification/Certification/Declaration, Optional Form 310
    e. Government Notice for Handling Proposals (as applicable)

2. SUBMIT WITH BUSINESS PROPOSAL

    (Submit with original and every copy of business proposal)

    a. Proposal Summary and Data record, NIH-2043

(Submit with the original only)

b. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original.
c. Representations and Certifications

3. OTHER - TO BE SUBMITTED LATER:

a. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, (if required by the CO).
b. Small Business Subcontracting Plan, to be submitted as directed by the CO.

4. ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

a. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
b. Procurement of Certain Equipment, NIH(RC)-7
c. NIH Women and Minority Policy
d. Protection of Human Subjects Assurance, Identification/Certification/Declaration, Optional Form 310
e. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects
f. Small Business Subcontracting Plan

PROPOSAL INTENT RESPONSE SHEET **[Back to Cover Letter]**

RFP NIMH-00-AI-0005

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **March 7, 2001**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

☐ DO INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING:

_____
_____
_____

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

_____
_____
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

_____
_____
_____
_____

RETURN TO: National Institute of Mental Health, NIH
Contracts Management Branch
Attn: Bruce E. Anderson
Neuroscience Center Bldg., Rm. 6107
6001 Executive Blvd. (MSC 9603)
Bethesda, MD 20892-9603
FAX (301) 443-0501
ba9i@nih.gov